

Amendments to the Specification

Please replace the paragraph beginning at page 5, line 4, with the following rewritten paragraph:

Performing the above-discussed steps can be difficult for patients, especially for patients with limited hand dexterity, such as the elderly. In a typical procedure, the patient first creates an incision in the skin by lancing the skin with a lancet. When the incision is being formed, the skin can tend to deform or bulge such that the lancet forms an incision with a greater depth than needed. As one should appreciate, the greater penetration depth of the lancet into the skin results in more pain associated with lancing for the user. Once a sufficient amount of fluid collects as droplet on the skin, the patient has to position a test strip over the [[cite]] site such that the test strip contacts and absorbs a sufficient amount of the droplet for testing. In another collection technique, the user positions a capillary tube over the incision [[cite]] site and transfers the fluid from the incision onto a test strip with the capillary tube. Usually the droplets of fluid are quite small, and patients, especially ones with hand motor control problems, may experience great difficulty in positioning the test strip or capillary tube so as to collect a sample from the droplet. Moreover, the incision may be closed when excessive pressure is applied to the skin by the test strip or capillary tube, thereby reducing the fluid supply from the incision. As should be appreciated, patients can become frustrated by this procedure, and consequently, they may perform the test less often or may even quit testing altogether.

Please replace the paragraph beginning at page 10, line 9, through page 11, line 5, with the following rewritten paragraph:

In a further embodiment, the lancet is slidably received inside the capillary channel. The lancet in this embodiment is generally flat. By being positioned inside the channel, the lancet is supported and stabilized by the housing throughout the entire lancing stroke so that the lancet remains in proper alignment during lancing. The support provided by the housing around the lancet prevents the lancet from laterally deflecting or bending during lancing, which in turn prevents the incision from being formed at the wrong location or angle. As will be appreciated from the discussion below, this design also allows the flat lancet to be formed from thinner material than previously possible, which in turn ~~may reduce~~ may reduce the pain associated with lancing.

Moreover, this configuration ensures that the capillary channel is positioned directly over the incision. The device further includes retraction mechanism for retracting the lancet into the housing after lancing the skin. During lancing, the lancet extends from the opening of the capillary channel so as to form an incision in the skin. In one form, the device has a skin contacting edge positioned next to the opening of the capillary channel in order to provide a reference surface for flattening the skin around the lancet. By flattening the skin around the lancet, an incision with a precise depth can be formed. In a further form, the device incorporates an adjustment mechanism for adjusting the penetration depth of the lancet. Once the skin has been lanced, the retraction mechanism withdraws the lancet back into the housing. The bodily fluid from the incision is then drawn into the channel and around the lancet via capillary action. As should be appreciated, by having the lancet positioned within the capillary channel, the opening of the capillary channel is positioned over the incision [[cite]] site before lancing. This eliminates the need to reposition the capillary over the incision subsequent to lancing the incision. After the fluid has been drawn within the capillary channel, the fluid is then transported to a means for testing the fluid, such as a test strip.

Please replace the paragraph beginning on page 26, line 4, with the following rewritten paragraph:

To insert device 330 into holder 360, the actuation gear 378 rotates the wheel 380 such that gap 380 is positioned over the slot 384. Device 330 is then slid into the receptacle 364 so that the head 346 of the device 330 is slid past slot 384. Next, the actuation gear 378 rotates the wheel 380 such that at least one of the steps 382 is positioned in the slot 384 between the head 346 and the sampling portion 348 of device 330, thereby securing the device 330 to the holder 360. The step 382 with the appropriate thickness can be positioned in the slot 384 between the head 346 and the skin contacting portion 348 so as to control the penetration depth of the blade 334. During lancing, as the holder 360 is driven towards the skin, the skin contacting edge 354 contacts the surface of the skin and flattens the skin around the incision [[cite]] site, thereby providing a suitable surface from which to gage the penetration depth of the blade 334. As the holder 360 is driven further, the skin contacting portion 348 of the housing 332 slides within the receptacle 364 towards the head 346 of the device 330 such that the blade 334 is uncovered to lance the skin. The skin contacting portion 348 of the housing 332 continues to retract until it

engages the selected step 382 on the wheel 380. As previously mentioned, the thickness of the step 382 controls the penetration depth of the blade 334. After the incision is formed, the leaf spring 350, which became flexed during lancing, extends portion 348 of the housing 332 so as to recover the blade 334. As the bodily fluid from the incision forms a drop on the skin, opening 353 of device 330 is positioned proximal the incision in the skin. In one embodiment, the skin contacting edge 354 of device 330 remains in contact with the skin as the drop of fluid forms. In another embodiment, the skin contacting edge 354 is positioned proximal the skin to collect the drop of fluid. The fluid is then drawn via capillary action inside the blade cavity 344. Next, the fluid travels through the blade cavity 344 and is deposited on the test media 336 for analysis.

Please replace the paragraph beginning on page 9, line 12, with the following rewritten paragraph:

The present invention generally concerns an integrated skin lancing device that reduces the number of steps involved in collecting and analyzing bodily fluid samples. The device includes a lancet for forming an incision in the skin as well as a housing that defines a capillary channel for drawing fluid from the incision onto a test strip located in the housing. In one form, the device has an overall flat shape such that manufacturing of the device is simplified so that its components can be laminated together to form the device. With the integrated design, the user does not have to reposition or reorient a capillary tube or a test strip over the incision in order to draw and analyze a sample.

Please replace the paragraph beginning on page 9, line 20, through page 10, line 8, with the following rewritten paragraph:

In one embodiment, one or more spacer members are sandwiched between a base member and a sheet of flexible, hydrophilic film so as to define the capillary channel with an opening. The lancet is attached to the base and has a tip for lancing that extends past the opening of the capillary channel. In one particular form, the hydrophilic film extends past the opening of the capillary channel so as to promote wicking of the bodily fluid sample into the channel. Due to its flexible nature, the hydrophilic film bends against the skin during lancing. After the skin is

lanced, the hydrophilic film remains in contact with the skin, and the fluid is drawn via capillary action between the hydrophilic film and the lancet's tip. Since the hydrophilic film is flexible, the film does not significantly deform the skin such that the incision in the skin remains open during collection of the fluid sample. If the hydrophilic film were rigid, however, the skin would tend to deform such that the incision would prematurely close, thereby cutting off the fluid supply. Moreover, one of the many benefits of having the lancet already positioned proximal the opening of the capillary channel is that the opening of the channel does not have to be repositioned over the incision after lancing. The integrated lancing device further includes a testing means positioned along the capillary channel for analyzing the bodily fluid sample. In one form, the testing means includes a chemical reagent test strip. The testing means in another form includes two or more electrodes that are operatively coupled to an electrochemical reagent test strip.

Please replace the paragraphs beginning on page 10, line 9, through page 11, line 14, with the following rewritten paragraphs:

In a further embodiment, the lancet is slidably received inside the capillary channel. The lancet in this embodiment is generally flat. By being positioned inside the channel, the lancet is supported and stabilized by the housing throughout the entire lancing stroke so that the lancet remains in proper alignment during lancing. The support provided by the housing around the lancet prevents the lancet from laterally deflecting or bending during lancing, which in turn prevents the incision from being formed at the wrong location or angle. As will be appreciated from the discussion below, this design also allows the flat lancet to be formed from thinner material than previously possible, which in turn may reduce may reduce the pain associated with lancing. Moreover, this configuration ensures that the capillary channel is positioned directly over the incision. The device further includes a retraction mechanism for retracting the lancet into the housing after lancing the skin. During lancing, the lancet extends from the opening of the capillary channel so as to form an incision in the skin. In one form, the device has a skin contacting edge positioned next to the opening of the capillary channel in order to provide a reference surface for flattening the skin around the lancet. By flattening the skin around the lancet, an incision with a precise depth can be formed. In a further from form, the device incorporates an adjustment mechanism for adjusting the penetration depth of the lancet. Once

the skin has been lanced, the retraction mechanism withdraws the lancet back into the housing. The bodily fluid from the incision is then drawn into the channel and around the lancet via capillary action. As should be appreciated, by having the lancet positioned within the capillary channel, the opening of the capillary channel is positioned over the incision cite before lancing. This eliminates the need to reposition the capillary over the incision subsequent to lancing the incision. After the fluid has been drawn within the capillary channel, the fluid is then transported to a means for testing the fluid, such as a test strip.

As will be appreciated from the discussion below, the number of steps involved in obtaining a sample is significantly reduced using the integrated device according to the present invention. The capillary channel in the integrated device does not have to be repositioned over the incision after lancing. Consequently, the difficulties associated with moving a capillary tube quickly and accurately to the incision site ~~is~~ are significantly reduced. It therefore enhances the ability to acquire the expressed body fluid without loss, delay or contamination. Moreover, the devices according to the present invention are useful for sampling and analyzing various type bodily fluids. For example, the devices can be suitable for sampling either blood or interstitial fluid.